Patient Access and Monitoring Form

Genzyme Corporation, a Sanofi Company, and its affiliates (hereinafter collectively referred to as the "Company") will donate US labelled Campath (the "Product") to The Sanofi Foundation and thereby make it available to eligible patients through the Campath Access Program.

For all enquiries regarding the access program, please contact Clinigen by email (customer.services@clinigengroup.com), or telephone & fax using the details in section 5

Instructions for completion

For **ALL** Product requests, you must complete **Section 1a, 1b, 3 & 4.**

To request supply of the Product under the Campath Access Program, this Patient Access and Monitoring Form must be read, completed and signed by the prescribing physician and where necessary the hospital/pharmacist.

To submit a request **to reassign unused product at your institution** to the patient below, following approval of eligibility under the Campath Access Program, please complete **Section 2.**

To request **continuation or maintenance treatment** for an individual already enrolled in the Campath Access Program, please contact Clinigen who will provide you with the relevant form..

Responsibility to the patient

Informed consent must be obtained from the patient before any treatment is started. The patient should be supplied with all relevant Product information, informed that the Product is not licensed, and is supplied to meet a special need identified by the patient's physician with the approval, as appropriate, of the national regulatory authority.

Appropriate consent from the patient will be obtained from the patient regarding the processing of any personal data in connection with the Campath Access Program, and communication of such data to third parties (e.g. national regulatory authorities, Clinigen / the Company) the use of the data in reports and studies and any other activities necessary for the proper execution of the Campath Access Program.

As the prescribing physician you accept personal responsibility for obtaining all necessary consents from the patient you accept medical responsibility for the use of the Product and all communication with the patient relevant to the request for treatment. Any communication received by Clinigen from the patient will be forwarded to the prescribing physician responsible for the treatment of the patient.

Safety Information: collection and reporting

The Company and Clinigen will comply with pharmacovigilance legislation which includes the collection and reporting of adverse drug reactions (ADR's) and other relevant safety information to all relevant regulatory authorities (where required). To comply with this legislation:

The prescribing physician must follow all applicable national pharmacovigilance regulations.

At a minimum, the prescribing physician must report - directly to the Company and within one business day – any adverse events for which the treating physician suspects at least a possible causal relationship with the use of the Product (Adverse Drug Reaction (ADR)) and/or safety information*.

Details of the ADR or other safety information must be submitted to the Company using the ADR Form, which will be provided with each Product delivery. Reporting details, such as entity name, fax (001 (617) 761-8506), telephone, and e-mail information (pharmacovigilancesafety@genzyme.com) are provided on the ADR Form.

*Safety information includes all (serious) adverse events and any information regarding misuse, abuse, medication errors, overdose, lack of efficacy and exposure to the Product during pregnancy and transmission of infectious agents via the Product.

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Section 1a: Patient Information (required)					
Patient initials*		Date of birth*		Clinigen patient ID [completed by Clinigen]	
Diagnosis					

Alemtuzumab should not be administered to patients with known hypersensitivity to Alemtuzumab or murine proteins, known HIV positivity, active systemic infections, active second malignancies or pregnancy/lactation. Please tick to confirm that you will not administer Alemtuzumab to patients with any of the above conditions. ☐

Intended Use

Chronic Lymphocytic Leukaemia (CLL) ☐
T cell Prolymphocytic Leukaemia (TPLL) ☐
Peripheral T cell Lymphoma (PTCL) ☐
Cutaneous T cell Lymphoma (CTCL) ☐
Mycosis Fungoides ☐
Sezary Syndrome ☐
T cell Lymphoma NOS ☐
T cell Large Granular Lymphocytic Leukaemia (TLGLL) ☐
Refractory/Steroid Resistant Graft versus Host Disease (srGVHD) ☐
Stem Cell Transplant Conditioning (HSCT) and/or Graft versus Host Disease Prophylaxis

- Use Associated with Institutional Clinical Protocol ☐
- Outside of Institutional Clinical Protocol (***Medical review required***) ☐

Solid Organ Transplant Induction Therapy (SOT); *please specify organ*_____

- Use Associated with Institutional Clinical Protocol ☐
- Outside of Institutional Clinical Protocol (***Medical review required***) ☐

Hematologic malignancy or other condition for which conventional therapies have failed, are unsuitable, or are unavailable.(***Medical review required for all the below indications***)

- CLL- Autoimmune Hemolytic Anemia (AIHA) ☐
- Refractory/Steroid Resistance Solid Organ Transplant Rejection ☐
  ***please specify organ*_____**
- Aplastic Anemia (AA) ☐
- Hemophagocytic lymphohistiocytosis (HLH) ☐
- Other Lymphoma, ***please specify***_____
- Other Leukaemia, ***please specify*** _____
- Other, ***please specify***_____

Campath dose ***		Anticipated date of initiation**		Campath schedule	
No. of 30mg vials initially requested for this patient ****			Total No. of 30mg vials anticipated to be requested for this patient		
Line of therapy	1st line therapy ☐ 2nd/3rd line therapy ☐ 4th/5th/6th line therapy ☐		Regimen	Single agent therapy ☐ Combination therapy ☐	

**This information is required by Clinigen to generate a unique patient identifier for each new patient. The data will be treated as confidential.*
***Product should be requested at least 1 week prior to the necessary continuation treatment.*
**** Please note that if the dose is above 30mg/ml section 1b) must be completed. The vial contains no preservatives and is intended for single use only. DISCARD VIAL including any unused portion after withdrawal of dose.*
*****Please note that there are restrictions on the maximum number of vials that will be shipped.*

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Section 1b: Patient Treatment History (required)			
Please tick to confirm that the patient has a condition for which conventional therapies have failed, are unsuitable or are unavailable either as marketed products or through enrolment into clinical trials. Patients not meeting these criteria may not be eligible for access to Campath.			☐
Patient's current disease status			
Do you intend to use Campath in combination with other therapies?		☒ No ☐ Yes please specify regimen:	
Did the patient receive any prior therapies to treat the above condition?		☐ No ☒ Yes please specify below	
Prior therapy regimens	Date of therapy	Response	Duration of response
Please provide additional information that should be considered in review of this request for Campath			

Section 2: Vial Reassignment (optional)			
Number of remaining vials to be reassigned		Clinigen patient identifier previously assigned to vials (if applicable)	
Reason for unused vials	Original patient not treated Treatment halted Early SOT Inventory Reallocated		☐ ☐ ☐

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Section 3: Physicians Declaration (required)

Declaration by Prescribing Physician - by signing this Access Form I make the following declarations:

1. I have requested, in accordance with the laws in my country, supply of the Product for the above-mentioned patient who cannot be adequately treated with medications approved or available through clinical trials in my country at this time. I will only prescribe and use this supply for the above-mentioned patient.
2. I confirm that this request is not for treatment of a multiple sclerosis patient and I understand that if I am seeking the Product for treatment of a multiple sclerosis patient, I should contact the Company's Medical Information Department using the numbers in section 6.
3. I confirm that I will not use the Product as first line therapy for the following indications: Multiple Myeloma, Follicular Lymphoma, Hepatosplenic Lymphoma, Angioimmunoblastic Lymphoma, NK and NK T cell Lymphoma, Hodgkin's Lymphoma, Anaplastic Large cell Lymphoma, Diffuse Large B cell Lymphoma, and/or Acute Lymphoblastic Leukaemia.
4. I have informed my patient that this is an unlicensed medicine and that there are risks involved in the use of unlicensed medicines.
5. I confirm that I have read and understood Genzyme's Product information supplied by Clinigen. I have provided all relevant Product information to the patient, have answered his/her questions and will obtain informed consent prior to the first administration of the Product.
6. I confirm that I understand and acknowledge the dosing guidelines including pre-medications and anti-infective prophylaxis.
7. I declare that this Product will be administered under my direct personal responsibility.
8. I acknowledge that I am responsible for reporting any adverse effect to regulatory authorities (as required) and the Company, and any other safety information that may arise from the administration of the Product. I agree to give prompt attention to any request for follow-up information.
9. I agree to collate data on previous and planned infusions as laid out on the forms provided and return this to Clinigen in order to replenish Product supply.
10. I agree to destroy any unused Product and provide documentation to confirm Product destruction.
11. I am aware that this Product should be kept in a 2-8 °C environment.
12. I confirm that I have asked and obtained consent from the patient processing of any personal data in connection with the Campath Access Program, and communication of such data to third parties (e.g. national regulatory authorities, Clinigen / the Company/ The Sanofi Foundation the use of the data in reports and studies and any other activities necessary for the proper execution of the Campath Access Program.
13. I understand that the Company will have the right, but not the obligation, to audit and I agree to the Company's right to audit my clinical and prescribing information for compliance with the above declarations.

Treating Physicians Details			
Physician Signature		Date	
Name & Title		License Number	
Telephone		Department	
Email		Hospital	
Fax		City	

SANOFI Foundation for North America

CLINIGEN A Specialty Pharma Group

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Section 4: Supply & Delivery (required)

Supply of the Product is subject to applicable national regulatory requirements, which may include direct approval from your national regulatory authority, and compliance with the requirements described in the "Declaration by the Prescribing Physician".

The Company and The Sanofi Foundation reserve the right to not supply the Product to a particular physician or to halt the Campath Access Program altogether at any time.

Reasons for this action may include, but are not limited to:

1. Previously unknown, unexpected and/or serious safety concerns arise.
2. The terms of the Campath Access Program, including the declarations, are not adhered to.
3. Required based on changes to local regulatory requirements governing access to unlicensed medicines.

Delivery Details			
Pharmacist		Telephone	
Email		Fax	
Hospital/ Pharmacy		Country	
City		Street/Postal Code	
Opening hours		Out of hours telephone	

Section 5:Contact Information

CLINIGEN (for all inquiries regarding the program)
***If your country is not listed below, please use the UK contact numbers**

Country	Telephone Number	Hours of Operation and Time Zone	Fax Number	Language
UK*	**+44 1283 494 340**	**9am-5pm (GMT)**	**+44 1283 494 341**	**English, Dutch, Russian, Romanian, Portuguese, Guarani, Belarusian**
Belgium	065 250 307	9am-6pm (CET)	+44 1283 494 341	French
Brazil	0800 7610752	8am-3pm (BRT)	+44 1283 494 341	Portuguese
Canada	1 866 596 8940	8am-1pm (EST)	1 866 612 7741	English
France	0800 903 406	9am-6pm (CET)	0805 109 994	French
Germany	069 2222 3413	9am-6pm (CET)	0800 589 2457	German
Italy	800 977 669	9am-6pm (CET)	800 977 686	Italian
Spain	800 600 217	9am-6pm (CET)	800 600 218	Spanish/Castilian

SANOFI-GENZYME Medical Information

Country	Telephone Number	Hours of Operation and Time Zone	Fax Number	Email Address
USA and Canada	1-(800)-745-4447, option 2	8am-6pm (EST)	1-(617)-591-7178	medinfo@genzyme.com
Continental Europe, Eastern Europe, Africa and Middle East		8am-6pm (CET)	+31 35 699 1403	EUmedinfo@genzyme.com
UK	+44 (0)1865 405283	9am-5pm (GMT)	+44 (0) 1865 774172	uk-medicalinformation@sanofi.com
Asia Pacific (ex. Japan)	+65 64033480	8am-5:30pm (GMT+8)	+65 64033456	medinfoAsia@genzyme.com
Latin America	+55 21 2156 9950	9am-6pm (BRT)	+55 21 2156 9982	medinfo.latam@genzyme.com

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Section 6: Campath/MabCampath Label by country prior to license cancellation* (status of labels varies; may be active, cancelled or expired)	
(Mab)Campath is indicated for the treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate.	European Union
	Hong Kong
	Israel
	Iceland
	Macedonia
	Norway
Campath is indicated as a single agent for the treatment of B-cell chronic lymphocytic leukemia (B-CLL).	US
(Mab)Campath is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL).	Albania
	Argentina
	Australia
	Belarus
	Kazakhstan
	Korea
	Malaysia
	New Zealand
	Russia
	Ukraine
(Mab)Campath is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) who have been treated with alkylating agents and who have failed to achieve a complete or partial response or achieved only a short remission (less than 6 months) following fludarabine phosphate therapy.	Bosnia & Herzegovinia
	Columbia
	Costa Rica
	Croatia
	El Salvador
	Guatemala
	Honduras
	Mexico
	Panama
	Peru
	Serbia
	Singapore
	South Africa
	Thailand
	Uruguay
(Mab)Campath is indicated as a monotherapy to treat patients with chronic lymphocytic B-cell leukemia (B-CLL). Combination therapies with MabCampath have not been sufficiently studied.	Switzerland
Campath is a third line medicine for the treatment of patients with chronic lymphocytic leukemia (CLL) after identification of refractoriness or development of resistance to fludarabine. This approach is extensive to the cases that have not received alkylating agents and have become resistant to fludarabine, in view of the low rescue index of these chemotherapy agents.	Brazil
MabCampath (Alemtuzumab) is indicated for the treatment of patients with previously untreated progressive B-CLL. The effectiveness of MabCampath as a single agent for the treatment of patients with previously untreated B-CLL is based on progression-free survival (PFS), complete response (CR) and overall response (OR) rates. Currently no data are available that demonstrate an increased overall survival with MabCampath. MabCampath (Alemtuzumab) is also indicated for the treatment of B-CLL patients who have been treated with alkylating agents and who have failed fludarabine therapy.	Canada
MabCampath is indicated for the 2nd and 3rd line treatment of patients with CLL.	Turkey

**Note the licenses may or may not be active as dates of cancellations and expirations vary. Labels have been translated from local languages and interpretations may vary.*